

REMARKS

By this amendment, claims 14-16 have been amended, claims 17-24 have been added, and claims 1-13 have been cancelled. **The claims remaining in consideration are claims 14-24. The independent claims remaining in consideration are claims 14, 16, 17, and 19.** No new matter has been added by this amendment.

I. Claim Rejections under 35 U.S.C. § 112

A. Indefiniteness Based On Effective Amount

The Examiner rejected claims 1-9 and 14-16 as being indefinite as to “what effective amount of botulinum toxin type A would do in the method of treatment.” Applicant respectfully requests reconsideration of this rejection.

One of ordinary skill in the art would know that a “pharmaceutically effective amount” is the dose required to achieve the desired result in a particular patient, namely the alleviation of the pain associated with migraine, diabetic neuropathies, or other sensory related disorders through the inhibition of neurotransmitters in trigeminal neurons. *See e.g.* ‘008 Application, ¶ 0025. Furthermore, the specification on page 6, paragraphs [0027] and [0028] describe a specific biological example using an embodiment of the claimed method in which one (1) vial of botulinum toxin type A, which contains 100 Units, was reconstituted and transdermally applied. Given this information, one skilled in the art would be reasonably apprised of the metes and bounds of this embodiment of the invention. Namely, one skilled in the art would know the proper amount of botulinum toxin type A to administer to achieve the stated goals of alleviating the pain associated with migraine, diabetic neuropathies, or other sensory related disorders. In addition, the ordinary skilled practitioner would know that the particular dose for a given patient may be dependent upon, and would consequently account for, a variety of factors, including the degree of pain being experienced by the patient, the age of the patient.

B. Indefiniteness Based On Sensory Neuron Related Disorder

The Examiner rejected claims 1-6, 9, 14, and 15 as being indefinite for using the term "sensory neuron related disorder". Applicant submits that the term sensory neuron related disorder was sufficiently described throughout the specification as those disorders that caused by or are associated with the release of neurotransmitters from sensory neurons. Applicant provided two specific examples of such disorders: migraine and diabetic neuropathy. However, Applicant has cancelled claims 1-9, which utilized the term "sensory neuron related disorder". Claims 14 and 15 have been amended to be directed to the treatment of disorders associated with the release of neurotransmitters in trigeminal neurons. New claims 17-24 are directed to a method for inhibiting the release of neurotransmitters in sensory neurons. Applicant respectfully requests reconsideration of this rejection.

C. Indefiniteness Based On Electrophoresis

The Examiner rejected claim 9 as being indefinite in describing how electrophoresis is applied. Applicant has deleted claim 9, thereby rendering this rejection moot.

D. Indefiniteness Based On Lack of Antecedent Basis

The Examiner rejected claim 16 as being indefinite for failing to provide sufficient antecedent basis for the limitation "the topical cream". Applicant has amended claim 16 to delete the reference to "the topical cream" and add reference to the mixture created in the preceding step of the claimed method. Applicant respectfully requests reconsideration of this rejection.

II. Claim Rejections under 35 U.S.C. § 102(e)

The Examiner rejected claims 1-3, 5-7, 9, 14, and 15 under 35 U.S.C. 102(e) as being anticipated by Donovan (US 2004/0009180) (hereinafter "Donovane"). Applicant has cancelled claims 1-3, 5-7, and 9 by this amended. Applicant respectfully requests reconsideration of this rejection with respect to claims 14 and 15.

In asserting this rejection against claims 14 and 15, the Examiner appears to acknowledge that Donovan does not refer to the inhibition of neuropeptides such as calcitonin gene-related peptide or the specific inhibition of neurotransmitters in trigeminal neurons. Applicant respectfully submits that this fact renders this an improper §102 rejection with respect to claims 14 and 15 of the application. Furthermore, Applicant submits that Donovan's non-specific reference to treatment of disorders associated with neurotransmitter release is not suggestive of the inhibition of trigeminal-associated neuropeptides.

III. New Claims

Applicant has added new claims 17-24 by this amendment. These claims largely follow the basic steps outlined in the original specification and claims of the application, and, as such, do not introduce new matter to the application. Claim 17 is directed to a method of treating diabetic neuropathy, as discussed in paragraphs [0024] and [0025] of the application as originally filed. Claims 18-24 are directed to a method of inhibiting the release of neurotransmitters in trigeminal neurons. The steps included in this method are discussed throughout the specification as originally filed.


IV. Conclusion

It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite

prosecution of this application, he is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Response is respectfully requested.

Respectfully submitted,



By: H. Frederick Rusche, Esq., Reg. No. 45,061
Husch & Eppenberger, LLC
190 Carondelet Plaza, Suite 600
St. Louis, MO 63105
314-480-1500
314-480-1505 FAX